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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/675,820 | 09/30/2003 | Gary K. Michelson | 101.0093-01000 | 6670 |

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| EXAMINER | |
|---|---|
| SWIGER III, JAMES L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3733 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/12/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/675,820 | MICHELSON, GARY K. | |
| | Examiner | Art Unit | |
| | James L. Swiger | 3733 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/30/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 8-9, 11-16, 21, 38, 41-42, 44-45, 48-51, 53-55, 56-57, 59-63, and 65 of U.S. Patent No. 6,896,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim at least a body having a leading and an opposite trailing end, that move in relationship to one another, an opening that provides a pathway, two arcuate portions that are capable of being in a first and second positions oriented towards adjacent vertebral bodies, a shape that is generally oval shape, surfaces that are parallel, surfaces that may be angled, an exterior surface that is generally circular/elliptical, et al.

Further, the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Cauthen (US Pub 2003/0135220). Cauthen teaches a guard for use in spinal surgery having a body (12), having a leading end (17) and opposite trailing end (15), the body having a first portion (18) and a second portion (37) in a pivotal relationship with one another (see figs. 13 and 14), the proximate leading end (17) having an open and closed position. The first (18) and second (37) portions have at least in part opposed interior arcuate portion (14), respectively, and wherein the first and second portions define an opening for providing access to the disc space, a space that may be considered a tube and is adapted to provide access and guide therethrough a surgical instrument. The opening defined by the first and second portions of the body is

generally circular but may also be elliptical (see paragraph 0039). Also the body's exterior surface has opposed upper and lower surfaces that are in part arcuate as well; wherein the exterior surface of the body has opposed side surfaces that are also in part arcuate and generally parallel; these sides also generally provide and are capable of providing a circular or elliptical cross section when in both the open and closed positions. The device may also be considered angled in the open position, at any given point between fully closed and fully open. The first and second portions also cooperatively engage each other when in a closed position (refer to Fig. 12). Further Cauthen teaches first and second portions that move rotatably to one another via a hinge, as they are associated with one another (par. 0034). Cauthen further describes that the device is able to create a disc space, as an 'open position' because of the ability of the device to rotatably articulate, creating a height (par. 0012) and allowing other devices to pass through. This orientation is considered along the mid-longitudinal axis. The device may also be secured/locked (par. 0045, line 15), and also comprises a collar (26, par 0040). Cauthen also teaches a body opening that has a height between 6-24 mm (par. 0038). Note that as claimed the opening as required for an instrument is between 8-25mm. However the range for Cauthen's device is 6-24. Therefore the device of Cauthen, as it is smaller, would be able to work within the situation as claimed by the applicant, meeting the size constraints. Cauthen teaches an opening between 6-24mm and would by default be able to fit a device within the 8-20mm opening from the claimed invention. Further Cauthen teaches that the hollow tube may accommodate a bone removal device such as a reamer (disclosed in line 3 of paragraph 0038; or for an

implant driver, also considered an insertion instrument (disclosed in lines 4-5 of paragraph 00390; or further a spinal implant (line 5 of paragraph 0039). With regards to the implant being partially bioresorbable, Cauthen further teaches that the spinal implant may be coated with a biocompatible material such as hydroxyapatite, which is inherently biocompatible/resorbable, as it has a similar chemical composition as human bone. The implant itself may also be made of a metal such as titanium (Par. 0042).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Gruskin et al. (US 2003/0023209). Cauthen discloses the claimed invention except for an implant that is incorporated with a material to prevent scarring. Gruskin et al. discloses a substance, namely a cross-linked polysaccharide having a positive charge that allows for the wound site to heal with less scarring. (See par. 0010). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-scarring additive in view of Gruskin et al. to better allow the wound area to heal with less damage.

Claim 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen

'220 in view of Mansourt et al. (US 2003/0229401). Cauthen discloses the claimed method of the spinal implant except for an implant having an antimicrobial agent. Mansouri et al. discloses an anti-microbe agent to prevent the colonization of bacteria on the surfaces of the implant or other parts of the device, or more specifically while treating a non-metallic medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-microbal agent to prevent infection and a more successful surgical application. (par. 0010).

***Response to Arguments***

Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive. With regards to the argument that the axis passes through at least a portion of the pathway, the axis portion in Cauthen (approx @ 22) is considered to touch at least a portion of the pathway, e.g. on the edge portion of the pathway. As the axis traverses that portion, it is considered to pass through at least a portion of the pathway.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/2/2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER